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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,375	10/09/2001	Donald Gerald Stein	07157/239838 (5543-17)	5877

826 7590 04/23/2002

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	5

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/973,375	Applicant(s) STEIN ET AL.	
	Examin r Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application claims priority from Provisional Applications Serial No. 60/245798 and 60/239505.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roof et al. (43, 44, and 45, PTO-1449 submitted April 8, 2002) and Gee et al. (Re. 35,517, PTO-1449 submitted April 8, 2002) in view of Applicant's admission regarding the prior art in the specification (see page 2).

Roof et al. (43) discloses that progesterone possess ability to reduce significantly the cerebral edema associated with traumatic brain injury and facilitate cognitive recovery in a rat mammal. See the entire article especially abstract and introduction.

Roof et al. (44) discloses that progesterone has been shown to have neuroprotective effects in injured nervous system including the severity of postinjury cerebral edema. See the entire article especially abstract and introduction.

Roof et al. (45) discloses that progesterone is useful in the treatment of brain edema following contusion injury in male and female rats. See the entire article especially abstract and introduction.

Gee et al. discloses that progesterone derivatives including the particular progesterone metabolite, allopregnanolone, are useful in a pharmaceutical compositions and method for modulating brain excitability via gamma-aminobutyric acid (GABA). Gee et al. also discloses the effective amounts of progesterone derivatives to be administered within the instant claim, and various known pharmaceutical carriers in the compositions. See abstract, col.1-2, col.4 lines 30-39, col.9, col.13-14, Table 2, and claims 1 and 5.

The prior art does not expressly disclose the employment of the particular progesterone metabolite, allopregnanolone, in a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to the central nervous system (CNS).

Applicant's admission regarding the prior art in the specification (see page 2) teaches that the particular progesterone metabolite, allopregnanolone, also have neuroprotective properties modulating GABA receptor and increasing the effects of GABA, same as progesterone. See page 2 lines 10-15. Applicant's admission regarding the prior art also teaches that a traumatic brain injury to CNS is tightly associated with GABA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular progesterone metabolite,

allopregnanolone, in a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to the central nervous system (CNS).

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular progesterone metabolite, allopregnanolone, in a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to CNS since progesterone is known to be useful in a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to CNS according to the prior art. The particular progesterone metabolite, allopregnanolone, is also known to have neuroprotective properties modulating GABA receptor and increasing the effects of GABA, same as progesterone, which is further supported by the disclosure in Gee et al. that this particular progesterone metabolite, allopregnanolone, are useful in a method for modulating GABA. Moreover, a traumatic brain injury to CNS is known to be tightly associated with GABA according the prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular progesterone metabolite, allopregnanolone, would be useful in the claimed methods herein for treating a tramatic central system injury and decreasing neurodegeneration in a subject following a traumatic injury to CNS, as progesterone.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. A. Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 17, 2002

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GROUP 1200